

Attorney Docket No.: 030793-036100

Application Serial No.: 10/076,596

Page 2 of 23

AMENDMENTS TO THE CLAIMS:RECEIVED
CENTRAL FAX CENTER

MAR 20 2007

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) An apparatus for collection and lateral flow chromatography of an oral fluid, the apparatus comprising:

a housing having a cavity;

a capillary matrix extending from within the housing and protruding out from the housing having an exposed surface for receiving oral fluid;

a lateral flow chromatography strip within the housing, wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid and is in flow communication with the capillary matrix; and wherein the capillary matrix is composed of a material different from the material comprising the lateral flow chromatography strip; and

a blocking strip within the housing coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains is impregnated with at least one blocking agent.

2-52. (Canceled)

53. (Currently Amended) The apparatus of claim 1, wherein the blocking strip further comprises a detergent, a chelating agent, or a buffer, or mixtures thereof.

54. (Currently Amended) The apparatus of claim 53 1, wherein at least one blocking agent is selected from bovine serum albumin, deoxycholate, and n-lauroyl sarcosine.

55. (Currently Amended) The apparatus of claim 1, further comprising a conjugate strip within the housing coupled between the blocking strip and the lateral flow chromatography strip, wherein the conjugate strip contains lateral flow chromatography reagents.

56. (Canceled)

Attorney Docket No.: 030793-036100

Application Serial No.: 10/076,596

Page 3 of 23

57. (Currently Amended) The apparatus of claim 56 1, wherein at least the analyte is selected from the group consisting of antibodies to HIV, antibodies to HTLV, antibodies to *Helicobacter pylori*, antibodies to hepatitis, antibodies to measles, antibodies to mumps, antibodies to rubella, cotinine, cocaine, benzoylecgonine, benzodiazepine, tetrahydrocannabinol, nicotine, ethanol theophylline, phenytoin, acetaminophen, lithium, diazepam, nortryptiline, secobarbital, phenobarbital, theophylline, testosterone, estradiol, 17-hydroxyprogesterone, progesterone, thyroxine, thyroid stimulating hormone, follicle stimulating hormone, luteinizing hormone, transforming growth factor alpha, epidermal growth factor, insulin-like growth factors I and II, growth hormone release inhibiting factor, IGA₁ and sex hormone binding globulin, and other analytes including glucose, cholesterol, caffeine, cholesterol, corticosteroid binding globulin, PSA, DHEA binding glycoprotein, and combinations thereof.

58. (Previously Presented) The apparatus of claim 57, wherein at least one analyte is an antibody to HIV.

59. (Previously Presented) The apparatus of claim 57, wherein at least one analyte is an antibody to hepatitis.

60. (Previously Presented) The apparatus of claim 1, wherein the lateral flow chromatography strip contains lateral flow chromatography reagents.

61. (Currently Amended) The apparatus of claim 1, wherein the capillary matrix is paddle-shaped.

62. (Previously Presented) The apparatus of claim 1, wherein the capillary matrix has an average pore size ranging from about 40 μm to about 250 μm .

63. (Currently Amended) The apparatus of claim 1, ~~further comprising a housing having a cavity in which~~ wherein the lateral flow chromatography strip is at least partially disposed into the cavity of the housing.

64. (Previously Presented) The apparatus of claim 1, wherein the housing includes at least one inspection site providing visual inspection of reagents at selected sites on the lateral flow chromatography strip.

65. (Currently Amended) The apparatus of claim 1, further comprising:

Attorney Docket No.: 030793-036100

Application Serial No.: 10/076,596

Page 4 of 23

a conjugate strip within the housing coupled between the blocking strip and the lateral flow chromatography strip and contains lateral flow chromatography reagents;

~~a housing having a cavity~~, wherein the lateral flow chromatography strip extends into the cavity along the housing to an inspection site on the housing; and

at least one inspection site from an exterior of the housing to the lateral chromatographic strip to enable visual inspection of reagents at selected sites on the lateral chromatographic strip.

66. (Currently Amended) The apparatus of claim 65, wherein the capillary matrix protrudes out from the housing and is in flow communication with the lateral flow chromatography strip.

67. (Currently Amended) An apparatus for collection and lateral flow chromatography of an oral fluid, the apparatus comprising:

a housing having a cavity;

a collection pad of a capillary matrix extending from within the housing and protruding out from the housing having exposed surface for receiving oral fluid;

a blocking pad within the housing and coupled between the capillary matrix and a lateral flow chromatographic strip, wherein the blocking strip ~~contains~~ is impregnated with at least one blocking agent;

a conjugate pad within the housing and coupled between the blocking pad and the lateral flow chromatography strip, wherein the conjugate pad contains lateral flow chromatography reagents;

~~a~~ the lateral flow chromatography strip within the housing, wherein the lateral flow chromatography strip extends into the cavity along the housing to an inspection site on the housing; and

at least one inspection site from an exterior of the housing to the lateral flow chromatographic strip to enable visual inspection of reagents at selected sites on the lateral chromatographic strip; and

wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid and is in flow communication

Attorney Docket No.: 030793-036100

Application Serial No.: 10/076,596

Page 5 of 23

with the capillary matrix; and wherein the capillary matrix is composed of a material different from the material comprising the lateral flow chromatography strip;

a housing having a cavity, wherein the lateral flow chromatography strip extends into the cavity along the housing to an inspection site on the housing; and

at least one inspection site from an exterior of the housing to the lateral chromatographic strip to enable visual inspection of reagents at selected sites on the lateral chromatographic strip.

68. (Previously Presented) A kit for the detection of an analyte in an oral fluid comprising:

the apparatus of claim 1; and

a buffer, reagent, or detection reagent for collection and lateral flow chromatography of an oral fluid.

69. (Previously Presented) A kit for the detection of an analyte in an oral fluid comprising:

the apparatus of claim 67; and

a buffer, reagent, or detection reagent for collection and lateral flow chromatography of an oral fluid.

70. (New) The apparatus of claim 53, wherein the chelating agent is EDTA.

71. (New) The apparatus of claim 1, wherein at least one blocking agent is selected from bovine serum albumin, deoxycholate, and n-lauroyl sarcosine and wherein the chelating agent is EDTA.